

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Empowering people with type 2 diabetes family-based approach - central

#### Protocol summary

##### Summary

Diabetes mellitus is a chronic disease with high prevalence and is a growing concern in the world. Several factors in the care of people with chronic diseases such as diabetes that the concept of health literacy known as an important factor on diabetes mellitus. Although diabetes is one of the most important socio-economic and health concerns and help diabetic patients for good glycemic control and prevention of complications of disease is related to the patients health literacy and self efficacy. Considering the fact that the relationship between support and family education and diabetes, few studies about patients with type 2 diabetes and most of the research done in this regard on children and youths in Iran, also according to the characteristics unique Iranian families and the culture of governing, little research has been reported in this case. The aim of this study was to determine the effect of family-centered empowerment model on health literacy and self-efficacy in people with type 2 diabetes. Inclusion criteria: age between 20 to 60 years old; no history for mental disorders; diagnosis for diabetes at least for one year; ability for reading and writing; not attending in another study by Patients and families; living with family; ability to talk and communicate with the family; no serious or debilitating complications of diabetes such as kidney failure and blindness and patient and caregiver agree to participate in the research. Exclusion criteria: no desire to continue cooperation and participate in the study; be suffering from mental illness or other chronic diseases; not having caregiver for the patients. In this study, the study population of diabetic patients referred to Imam Ali Shahr-e-Kord clinic was selected from among which 80 patients with type 2 diabetes were selected randomly and then assigned randomly into two groups of control and intervention (each group was 40 patients). In control group, routine training are received in the control group, but in the intervention group, family-based care is provided to the patient and the main care giver of the patient (family member), in 6 sessions Family-centered

empowerment will take place at intervals of one week and 90 minutes each session. The data gathering tool in this study was a questionnaire of health literacy and self-efficacy in diabetic patients who evaluated the level of health literacy and self-efficacy in the three stages before, immediately and three months after the intervention. Data is analyzed using software 23 and statistical tests such as paired t-test, independent t-test, chi-square

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201609252861N13**

Registration date: **2017-10-19, 1396/07/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-19, 1396/07/27

##### Registrant information

##### Name

Reza Masoodi

##### Name of organization / entity

Nursing department, Shahrekord University of Medical Science,

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 1333 5654

##### Email address

masoodi@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahrekord University of Medical Sciences

##### Expected recruitment start date

2016-09-25, 1395/07/04  
**Expected recruitment end date**  
2016-12-24, 1395/10/04  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Empowering people with type 2 diabetes family-based approach - central

**Public title**  
The Effect of program based on the family-centered model on health literacy and self-efficacy of people with type 2 diabetes

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
Inclusion criteria: age between 20 to 60 years old; no history for mental disorders; diagnosis for diabetes at least for one year; ability for reading and writing; not attending in another study by Patients and families; living with family; ability to talk and communicate with the family; no serious or debilitating complications of diabetes such as kidney failure and blindness and patient and caregiver agree to participate in the research.  
Exclusion criteria: no desire to continue cooperation and participate in another study during the study; be suffering from mental illness or other chronic diseases; not having caregiver for the patients.

**Age**  
From **20 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Shahrekord University of Medical Sciences

**Street address**

Shahrekord University of Medical Sciences

**City**

Shahrekord

**Postal code**

**Approval date**

2016-07-03, 1395/04/13

**Ethics committee reference number**

IR.SKUMS.REC1395.89

**Health conditions studied**

1

**Description of health condition studied**

Diabetes

**ICD-10 code**

E10-14

**ICD-10 code description**

Diabetes mellitus

**Primary outcomes**

1

**Description**

Health literacy

**Timepoint**

Pre intervention, 2 months after intervention

**Method of measurement**

Health literacy questionnaire

2

**Description**

Self efficacy

**Timepoint**

Pre intervention, 2 months after intervention

**Method of measurement**

Self efficacy questionnaire

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

This program is performed for the intervention group during six sixty-minute sessions and with a constant research team including internist, nurse internist and researcher. In each session, based on the content, paid attention to provide educational content, discuss patient experiences and treatments and illnesses problem. This care program is presented during discussion sessions

Also, through group discussion and telephone counseling, they will be in possession of an educational CD and some of them will be introduced to hospitals or charity associations. The researcher will discuss the treatment and care situation, the defects of their treatment and care knowledge and their support needs in this area, and provide guidance and action. Complete the questionnaire before and immediately after the intervention three months after the intervention.

**Category**

Behavior

**2**

**Description**

The control group only receives routine care and education. A researcher to observe ethical standards, after the end of the study, for the intervention group, invites control group patients to attend training sessions in a telephone call and Educational CDs (content provided during the Empowerment Program) will be delivered to them. The researcher's phone is also provided to them for further guidance.

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Diabetes Clinic located at the Imam Ali clinic

**Full name of responsible person**

Fatemeh Ghasemi

**Street address**

Imam Ali clinic, Shariati blvd.

**City**

Shahrekord

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Shahrekord University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research of Shahrekord University of Medical Sciences

**Street address**

Kashani Blvd-University Headquarters-second floor

**City**

Shahrekord

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Shahrekord University of

Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Fatemeh Ghasemi

**Position**

Master Student of Nursing

**Other areas of specialty/work**

**Street address**

Nursing and Midwifery School, Shahrekord University of Medical Sciences, Rahmatieh, Shahrekord

**City**

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**Phone**

+98 38 3338 9476

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**Email**

ghasemi.fatemeh87@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Dr. Reza Masoudi

**Position**

Assistant Professor/Ph.D in Nursing Education

**Other areas of specialty/work**

**Street address**

Nursing And Midwifery School, Shahrekord University of Medical Sciences, Rahmatieh, Shahrekord  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Fatemeh Ghasemi

**Position**

Master Student of Nursing

**Other areas of specialty/work****Street address**

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**City**

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**Postal code****Phone**

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*